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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,277	09/10/2004	Hiroshi Kasai	SHIGA8.001APC	3845

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/507,277	Applicant(s) KASAI, HIROSHI	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 9/26/2006 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2 and 5-6 have been canceled.
2. New Claim 14 has been added.
3. Claims 1 and 4 have been amended have been amended.
4. Remarks drawn to rejections under 35 USC 112, second paragraph, 102 and 103.

Claims 1, 3, 4 and 14 are pending in the case. Claims 7-13 have been indicated as withdrawn. This application contains claims 7-13 drawn to an invention nonelected with traverse in Paper No. 4/10/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 3-4 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendments to claims 3-4 and cancellation of claim 6.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Yanagawa et al (Nucleic Acid Symposium Series, 1991, 25, 113-114) has been overcome by amendments to the claim.

The following rejection is made of record necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagawa et al (Nucleic Acid Symposium Series, 1991, 25, 113-114) in combination with Park et al (Carcinogenesis, 1989, 10(5), 827-832) both of record.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Yanagawa et al teach the purification of 8-hydroxyguanosine (oxidatively damaged guanine nucleoside) from a nucleoside mixture (sample) comprising a first purification step by anion-exchange chromatography (page 113, right column, Materials and Methods). However, Yanagawa et al do not teach the purification of 8-hydroxydeoxyguanosine wherein the sample is urine and the use of a resin having a particle diameter of 7-12 microns.

Park et al, drawn to detection of DNA adducts, teach that guanosine ribonucleosides elute immediately before the corresponding deoxyribonucleosides in high performance reverse phase liquid chromatography (page 829, left column, 19-22 and Figure 2, page 828, right column, see under HPLC-EC). From this teaching one of ordinary skill in the art will recognize that based on the position of the hydroxyguanosine in the HPLC chromatogram the peak due to the deoxyguanosine can be easily identified. In other words hydroxyguanosine can serve as a marker for the corresponding deoxyguanosine. It can also be seen from the teaching of Park that reverse phase chromatography gives good separation of deoxyguanosine and Park also teaches that his method has a high degree of specificity and can be used for the quantization of damaged products not just in hydrolysates but also in urine.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to purify 8-hydroxydeoxyguanosine contained in a sample of urine as instantly claimed since the use of the two chromatographic methods individually for purification of the said compounds in a urine sample is seen to be taught in the prior

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art. It is well within the purview of one of ordinary skill in the art to use resin having the particle size as instantly claimed in order to optimize the purification efficiency.

One of ordinary skill in the art will be motivated to use the method as instantly claimed because the method is art tested and is seen to give good separation of the desired products from different samples including urine and the use of the particle size as instantly claimed will give a highly pure product free of even very minute sized contaminants. It is well known in the art and to one of ordinary skill in the art that the use of smaller sized resin particles will remove very minute sized contaminants.

Response to Applicants Arguments

Applicants have argued that claim 1 as amended recites that 8-hydroxyguanosine is purified from urine sample, while Yanagawa describe the purification of 8-hydroxyguanosine from Torula yeast RNA. Since the two starting samples are different the purification comprising anion exchange chromatography as a first step for the structurally similar 8-hydroxyguanosine from Torula yeast RNA sample would not necessarily be successful in purifying the same from a urine sample. There is no reasonable expectation of success and one of ordinary skill in the art would have no idea that it will work successfully for a urine sample based on Yanagawa's teaching.

Applicants' arguments are not found to be persuasive.

Yanagawa's method shows that 8-hydroxyguanosine can be separated from a mixture using anion exchange chromatography. The sample and their constituents may be different. But Yanagawa's teaching shows that the separation can be achieved with a reasonable amount of success, especially using the said method as a first step. The

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statement that it will not be successful for urine as the starting sample is just an opinion of the applicants that is not supported by any teaching. The instant claims as amended are rendered obvious by the prior art of record.

Conclusion

Claims 1, 3-4 and 14 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

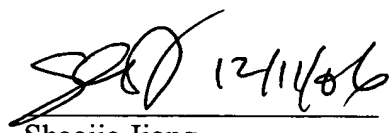
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Shaojia Jiang
Supervisory Patent Examiner
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